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(54) HEART VALVE PROSTHESIS

(71) We, ROBERT BERNARD DAVIS, of 11 Michael Road, Framingham, Massachusetts 01701, United States of America, JOHN SKELTON, of 11 Alden Street, Sharon, Massachusetts 02067, United States of America, RICHARD EDWIN CLARK, of 6 Thorndell Drive, St. Louis, Missouri 63117, United States of America, and WILBUR MILTON SWANSON, of 2301 Parkridge Avenue, St. Louis, Missouri 63144, United States of America, all citizens of the United States of America except John Skelton who is a citizen of the United Kingdom, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to a fabric for cardiovascular prostheses and particularly to heart valve replacements comprising fabrics supported on frameworks and forming a trileaflet configuration.

The replacement of heart valves with prostheses has become a standard surgical technique. However, the prostheses currently in use do not entirely satisfy the above objects. Currently, most prosthetic heart valves rely for closure on the sealing of a ball or a flap against a gasket ring. With this construction the ball or flap is situated within the flow channel when lifted away from the gasket in the flow configuration. This is disadvantageous in two important respects. First the pressure drop across the valve during the open or flow condition is greater than the pressure drop across the natural valve which causes a slight, but continuous and cumulative overload on the heart. Second, the presence of the ball or flap creates regions of turbulent flow tending to damage the red blood cells.

With the foregoing disadvantages in mind, research has been directed to developing leaflet valves more closely approximating the structure and functions of the human valve. The latter comprises thin, flexible membranes that fold flat against the wall of the surrounding blood vessel in the open configuration, thus causing a minimum of disturbance to the flowing blood. In the closed configuration the leaflets form three contiguous pouches that are held in close and leakproof contact by the pressure of the blood. As a result of the extreme lightness and flexibility of the leaflets the valve has a short response time, passing quickly from the fully closed to the fully open state, with the result that there is little energy loss in the flowing blood and a minimum of undesirable regurgitation.

These functional characteristics of the human valve result from the composite structure of the natural leaflet. This comprises an arrangement of bundles of collagen fibres embedded in a softer tissue material. The composite structure gives the leaflet good load bearing capacity, a high resistance to tear and sufficient softness and flexibility to make a good seal in the closed configuration. At the peak of the pressure pulse, the leaflet withstands a load exceeding 150 gm/cm along a line therein normal to the load.

Heart valve tissue is also anisotropic in its elastic properties, that is, the load-deformation characteristic in one direction is different from that in another direction. It has been found useful to define two particular directions for purposes of this description. These directions are parallel and perpendicular to the free edge of the leaflet, and correspond respectively to the circumferential and radial directions commonly referred to in the literature.

In the direction parallel to the free edge the natural leaflet extends very readily with increased load until an elongation of ten to twelve percent is reached at a load of one to two grams per centimetre of leaflet width.

Upon further increase in load the resistance to further elongation increases greatly. In the direction perpendicular to the free edge the region of easy extension with increased load continues to approximately 20 percent elongation, at which the load is about 2gm/cm. Upon further increases in load the resistance to further elongation, though greater than in the initial region, is not as high as it is in the parallel direction.

A recent development involves the use of stabilized pig heart valves as replacement for failing human valves. These valves embody some of the characteristics of human valves discussed above. However, the collection, grading, sterilizing, fixing and storing of pig valves is complicated and costly. In consequence a clear need has been realised for a trileaflet heart valve made entirely from synthetic materials.

According to one aspect of this invention there is provided a fabric for cardiovascular prosthesis comprising woven multi filament polymeric yarns extending in first and second directions forming an angle therebetween and having a substantial number of open interstitial spaces having dimensions in the range 20—40 microns evenly distributed throughout the fabric, the stretch characteristic of the fabric having a region of easy elongation up to at least 10% in at least one of said directions.

Preferably the yarns in each of said directions have crimps similarly oriented with respect to the plane of the fabric and being bloomed in their intersticies forms open interstitial spaces.

According to another aspect the invention includes a heart valve prosthesis comprising a frame having a plurality of mutually spaced generally parallel legs, each leg comprising a pair of rod portions connected at one end thereof, the rod portions of each leg diverging at the other end to connect with lobes respectively connected with a rod portion of another leg, the lobes forming an aperture therebetween and a plurality of flexible porous fabric leaflets consisting of the fabric hereinbefore defined, each leaflet being inserted between the rod portions of two of said legs, being sealed to said legs and to the interconnecting lobe and having a free edge extending between said legs, the free edges of said leaflets being deflectable into mutual contact for sealing said aperture.

The porous fabric leaflets are not required to be separate but may be formed from a single piece of fabric as hereinafter more fully described.

Preferably the fabric is compressively shrunk that is compacted in a first direction to form crimps in the yarns, the crimps being formed and heat set to lie in planes generally parallel with the fabric, and the yarns are bloomed in the interstices to form spaces of varying sizes and orientations between the filaments. This compressive shrinking step is then repeated in a second direction forming an angle with the first direction.

Preferably, the fabrics are woven either in the form of ribbons having a selvage of uncut yarns, this selvage forming the free edge of the heart valve leaflet.

The foregoing and other features of the invention are described more fully in the following description with reference to the appended drawings.

In the drawings:

Figure 1 shows the main frame of the preferred form of the heart valve.

Figure 2 shows a fabric ribbon in the configuration formed by inserting it into the main frame between the rod portions of its legs.

Figure 3 shows the second frame.

Figure 4 is a top plan view of the frame shown in Figure 1.

Figure 5 is a top plan view of the frame shown in Figure 3.

Figure 6 shows the partially fabricated heart valve with the fabric inserted into the main frame and cut open preparatory to cementing thereto.

Figure 7 is a developed view of the partially constructed heart valve, corresponding to Figure 6.

Figure 8 is a cross-sectional view taken on line 8—8 in Figure 7.

Figure 9 illustrates a flat braided fabric pattern.

Figure 10 is a photograph showing a plain woven multifilament polymeric fabric prior to compressive shrinking.

Figure 11 is a photograph showing the fabric of Figure 10 after compressive shrinking in the warp and weft directions.

Referring to the drawings, Figure 10 shown one form of starting fabric 12 having warp yarns 14 and weft yarns 16. The warp and weft yarns are each formed of untwisted filaments 18 of a polyester, for example, polyethylene terephthalate. For illustration, the fabric may be woven with approximately 100 yarns per inch in each direction, the yarns being about 30 denier. Each yarn contains 30 filaments 18, each filament having a diameter of about 10 microns. Because the yarns have no twist, as shown in the woven form of Figure 10 they have a flattened configuration. Consequently, the fabric is only about 3 to 4 filament-diameters thick. Also, as further explained below, the fabric is preferably woven with at least one selvage having no cut yarns. For this reason the fabric is advantageously woven in the form of a ribbon, although this is not a necessity.

Commercially available polyester yarn generally contains a number of impurities that make it potentially damagaing to the

body if used in implanted prosthetic devices. These impurities include residual catalyst from the polymerization process, oligomers, antioxidants and other stabilizers, delusterant and surface finishes. Accordingly, it is important to employ a pure polymeric material.

As shown in Figure 10 the yarns 14 and 16 are woven so as to provide interstices 20. These interstices have a role in the subsequent shrinking and crimping process steps described below, which are performed on the fabric of Figure 10 to produce the bilaterally crimped form shown in Figure 11. In successive steps, the fabric is shrunk, in two directions by compacting it while subject to in-plane compressive stress, each step being substantially as described for example in U.S. Patent No. 3,001,262 dated September, 26, 1961, to Charles Schwabe Parker and Alexander Melville. A machine may be used similar to that described in U.S. Patents Nos. 2,765,513 and 2,765,514, both dated October 9, 1956, and both to Richard R. Walton. The shrinking steps produce crimps in the yarns and cause them to bloom or spread out in the interstices of the woven pattern.

In order to produce the desired easy stretch characteristics in both directions, similar to those of the natural valve leaflet, the same woven fabric is compacted in both the warp and weft yarn directions sequentially. In this respect, the present process is in contrast to the technique described in the above patent to Parker et al, wherein the yarns of a first woven fabric are crimped in the warp direction, the fabric is then unravelled and the warp yarns are used as the weft or filling yarns of a subsequentially-woven fabric, the latter still later being crimped in the warp direction to give a two-way stretch characteristic. As a result of the present process the crimps in the yarns in both the warp and weft directions are formed and heat set to lie in planes generally parallel with the fabric, and the yarns are bloomed in the interstices to form spaces of varying sizes and orientations between the filaments. A substantial number of these latter spaces have dimensions in the range of 20 to 40 microns which is preferred for rapid tissue ingrowth, and are produced in an even distribution throughout the fabric. Thus the completed fabric is relatively thin as compared with the final fabric of Parker et al wherein the crimps and bloomed filaments of the final weft or filling yarns are necessarily displaced and reoriented during the second weaving relative to the plane of the fabric and the interstitial locations in the final weave.

The desirability of a thin fabric over a thicker one has been recognized as the result of the functional characteristics desired, in particular the flexibility and stretch characteristics, the non-thrombogenic property and the capability of withstanding many millions of flex cycles without fatigue failure. Non-thrombogenic properties are imparted to the fabric described herein by promoting tissue ingrowth so that the flowing blood is in contact only with naturally-occurring, compatible surfaces. Thus the filaments in the fabric become analogous to the bundles of collagen fibres in the natural leaflet, and provide a textile scaffold or lattice onto which and into which, the body can deposit tissue to provide the membrane function of the leaflet and the desired sealing properties. Although a clot is produced at the fabric-blood interface, the tissue ingrowth is such that the clot is firmly anchored to the fabric and does not break free into the bloodstream. Thus the fabric becomes completely embedded in a layer of living tissue that is thin enough to be nourished by diffusion processes.

It will be evident from the foregoing that the process of tissue ingrowth affects the thickness, and therefore the flexibility and stiffness of the functioning leaflet. In turn, these properties influence the susceptibility to fatigue failure and the ability to minimize regurgitation in the closed configuration. Also for effective use as a heart valve leaflet the fabric must have a region of very easy extension up to elongation levels in the range of 10 percent to 20 percent. In particular, as will be evident from the following description of Figures 1 to 8 each leaflet in the closed configuration is subjected to bending over a relatively sharp radius along a line perpendicular to its free edge. Along this line there is a region of high stress concentration.

An additional advantage of the present invention is illustrated by Figure 11 wherein it will be noted that the individual yarns are bloomed in the interstices 20; that is, the filaments are opened up locally in these interstices to provide a distributed matrix of smaller interstices of varying sizes and orientations. These promote tissue ingrowth. In contrast, a fabric such as that of Figure 10 has a regular configuration of spaced holes of relatively larger, fixed dimensions in which tissue ingrowth would not be as readily promoted.

The fabric manufactured according to the present process has been tested for tissue ingrowth, and has been shown to have performance superior in this respect to other available fabrics. It can be produced with the specific elongation characteristics needed for the leaflet application, and moreover such elongation characteristics may differ in two directions, such as the warp and weft directions.

The following is a more detailed description of the creping or compacting method employed according to this invention. Using the machine described in the above-men-

tioned patent Nos. 2,765,513 and 2.765,514, a ribbon of the woven fabric shown in Figure 10 approximately one and one-half inches wide and six inches long is placed between two sheets of paper and passed through the bite between a top roll and a bottom roll in the warp-wise direction. The top roll has a surface speed of 5.3ft/sec and the bottom roll has a surface speed of 1.1 ft/sec. During this compacting run the warp threads are shrunk or compacted to form crimps, these crimps being forced by the applied pressure of the rolls to lie in planes generally parallel with the fabric. At the same time the filaments of the warp threads are spread apart in the interstices between the weft yarns; that is, the yarns bloom in these interstices, thereby forming spaces of varying sizes and orientations, as shown in Figure 11.

Upon completion of this compacting step the fabric is removed from the paper sheets.

A second compacting run is then performed in a substantially identical manner to that described above, except that the fabric piece is passed through the bite of the rolls in the weft-wise direction.

If desired, each of the above-described compacting runs may be repeated, in which case the ribbon is preferably rotated though 90 degrees after each run.

The compaction steps in the two directions may be varied as to number and degree of compaction to produce the desired load-elongation characteristic in each of the two directions, thus approximating the corresponding characteristics of the natural leaflet. In any case, the compaction steps are such as to produce very easy extension up to elongational levels of 10 to 20 percent.

After the series of compacting runs, the fabric is heat set while in an unstressed state at a temperature below the fusion temperature. For polyethylene terephthalate a temperature of 410 degrees F. may be used, for example. The heat setting is preferably performed in a circulating hot air oven, and a typical time duration is one and one-half minutes.

In some cases it is desirable to treat the yarn prior to weaving in order to prevent damage to the filaments during the weaving process. A suitable method of treatment is a coating of 5 percent solution of polyvinyl alcohol. After weaving, this additive is washed out of the fabric in an aqueous wash.

We turn next to a description of the preferred form of trileaflet heart valve replacement. Referring to Figure 1 there is shown a main frame 22 comprising a single length of 0.1 c.m. diameter round polypropylene rod bent into a form having three mutually equidistant, generally parallel legs 24, 26 and 28, each leg comprising a pair of rod portions slightly spaced apart, the rod portions being connected at one end and diverging at the other end. The diverging rod portions form three lobes 30, 32 and 34. The connected ends of the rod portions in each pair form bights 36, 38 and 40. Figure 4 is a top plan view of the main frame 22.

A second frame 42 (Figures 3 and 5) is formed of a single length of 0.1 cm. diameter round polypropylene rod bent into a form having three lobes 44, 46 and 48 generally congruent with the lobes 30, 32 and 34 so as to fit in close contact therewith as shown in Figure 7.

The assembly is started by threading a bilaterally crimped and compacted ribbon 50, produced by the method described above and appearing as in Figure 11, through the three pairs of legs so as to produce the configuration shown in Figure 2. The frame 22 is shown in Figure 1 in exploded relation to Figure 2 for clarity of illustration. The upper selvage has no uncut yarns and forms the free edges 52, 54 and 56 of valve leaflets.

Thus a double layer of the fabric is passed through each pair of rod portions forming one of the legs 24, 26 and 28. It is necessary to attach the fabric firmly to these legs, and also to the connecting lobes 30, 32 and 34. To facilitate this attachment, the fabric is preferably cut lengthwise externally of each leg as shown in Figure 6. Referring to Figure 6, adhesive such a polyurethane dissolved in tetrahydrofuran is applied to attach the fabric to each of the legs as follows. Flaps such as 58 and 60 are spread apart and the adhesive is applied at the external point of juncture of the flaps where they enter between the rod portions, in a continuous line extending between points *a* and *b*. The adhesive material reaches to the external surfaces of the frame by penetration through the fabric flaps along this line; that is, the adhesive contacts the rod portions of the frame only on their outer surfaces. The leaflets comprise only those portions of the fabric on the inside of the frame, and these portions are not penetrated by the adhesive. Thus local stiffening and resultant flex failure caused by such adhesive penetration is avoided.

The above method of adhesive application also distributes the stresses of flexure evenly along the margins of the leaflets, and avoids excessive stress concentrations. These margins are permitted to move upon each flexure over the rounded contours of the surfaces of the rod portions that are located on the inside of the frame, and that are not penetrated by the adhesive.

Also, this method of adhesive application reduces blood contact with the adhesive.

The attachment of the fabric to the lobes 30, 32 and 34 is next accomplished by first placing the second frame 42 adjacent those lobes with the fabric pieces passing therebetween as shown in Figures 7 and 8.

Adhesive 61 is then applied through the fabric and to the surfaces of both the main frame 22 and the second frame 42, in a continuous line extending between the points *b* of the respective legs and connecting these three points. As in the previous step, the adhesive material preferably does not penetrate any portion of the leaflet material lying within the main frame 22, and remains out of contact with blood passing through the valve.

The foregoing steps essentially complete the fabrication of the leaflet portions of the valve. The remaining steps of fabrication are for the purposes of facilitating the suturing of the prosthesis within the blood vessel. The excess fabric available on the outside of the frame can be rolled and consolidated along the junction line between the main and second frames to provide attachment points for stitches during surgical insertion.

The frame material is preferably polypropylene, although other materials have also been employed with success. Polypropylene has excellent flex endurance and chemical stability, but is difficult to attach by adhesive to other materials. To facilitate adhesion, the main and second frames 22 and 42 may be encapsulated with polyurethane by multiple dip coating. The resulting encapsulated frame components have proved to demonstrate the desired characteristics of polypropylene without structural failures or breakdowns at the adhesive junctures.

Valves employing the fabric described above have been tested in an accelerated fatigue tester to assess their long term endurance characteristics. Fatigue failures so induced have generally occurred in the region of greatest fabric flexure, that is, along a line in each leaflet that is perpendicular to its free edge and substantially equidistant between the contiguous legs. The failures have generally occurred by breakdown of the filaments in the yarns running parallel to the free edge of the leaflets. As a means of providing greater fabric strength along the last mentioned lines, woven fabrics may be provided with a greater number of load-bearing yarns in this direction. However, there is a limit to the increase that is possible using the plain woven pattern of Figure 10 without seriously disturbing the geometry of the fabric interstices.

An alternative fabric construction pattern having improved strength against such fatigue failure is illustrated in Figure 9. The fabric shown is a flat braided ribbon 62 comprising 3 sets of yarns, namely, a first diagonal set 64, a second diagonal set 66 and a longitudinal inlaid set 68. The yarns in each of the three sets are preferably multifilament untwisted yarns similar to those shown in Figure 10. The ribbon 62 is braided on a conventional flat braiding machine.

It will be noted that each selvage has uncut yarns and one of those becomes the free edge of each leaflet. Thus fraying of the free edges of the leaflets is avoided as in the example described above. In this embodiment both of the sets 64 and 66 perform the load-bearing function of a single set of yarns in the earlier-described fabric. The result is that a greater number of yarns have a significant component of load bearing capacity oriented parallel to the free edge.

The fabric 62 of Figure 9 is preferably formed by braiding the yarn sets 64 and 66 with inlaid longitudinal yarns 68 in a well-known manner, thus producing a type of triaxial fabric. Such flat braided fabrics have an additional advantage over conventionally woven fabrics, in that they are inherently highly extensible in the cross machine direction, that is, in the direction perpendicular to the yarns 68. Such fabrics make it possible to produce a two-way stretch characteristic with any desired combination of stretch capabilities by compacting in the direction of the yarns 68 only.

The frame system for a cardiovascular prosthesis described herein is described and claimed in our co-pending Application No. 22665/80 (Serial No 1598112).

WHAT WE CLAIM IS:—

1. A fabric for a cardiovascular prosthesis comprising woven multi-filament polymeric yarns extending in first and second directions forming an angle therebetween and having a substantial number of open interstitial spaces having dimensions in the range 20—40 microns evenly distributed throughout the fabric, the stretch characteristic of the fabric having a region of easy elongation up to at least 10% in at least one of said directions.

2. A fabric according to claim 1, the yarns in each of said directions having crimps similarly oriented with respect to the plane of the fabric and being bloomed in their intersticies to form said open interstitial spaces.

3. A fabric according to claim 1 or claim 2 in which said fabric has different elastic compliance in said first and second directions.

4. A fabric according to claim 1, 2 or 3 in which the yarns are flattened and essentially untwisted.

5. A fabric according to claim 4 having a thickness less than 4 filament diameters.

6. A fabric according to any one of the preceding claims in which said angle is a right angle.

7. A fabric according to any one of the preceding claims in which the filament diameters are 10 microns.

8. A fabric according to any one of the preceding claims in the form of a ribbon having a selvage of uncut yarns.

9. A fabric according to claim 8 wherein the ribbon is a flat braided ribbon.

10. A fabric according to claim 9 having longitudinal yarns extending parallel to the selvage and braid carrier yarns extending to the selvage at acute angles thereto.

11. A fabric for cardiovascular prosthesis substantially as hereinbefore described with reference to figures 9 or 11 of the drawings.

12. A heart valve prosthesis comprising a frame having a plurality of mutually spaced generally parallel legs, each leg comprising a pair of rod portions connected at one end thereof, the rod portions of each leg diverging at the other end to connect wih lobes respectively connected with a rod portion of another leg the lobes forming an aperture therebetween, and a plurality of flexible porous fabric leaflets consisting of the fabric of any one of the claims 1 to 11, each leaflet being inserted between the rod portions of two of said legs, being sealed to said legs and to the interconnecting lobe and having a free edge extending between said legs, the free edges of said leaflets being deflectable into mutual contact for sealing said aperture.

13. A heart valve prosthesis according to claim 12 wherein the frame comprises three mutually equidistant generally parallel legs and the leaflets are sealed to the frame by adhesive applied externally of the aperture.

14. A heart valve prothesis according to claim 12 or 13 in which the filaments forming the fabric are uncoated and adapted to promote formation of a layer of living tissue that is sufficiently thin to be nourished by a diffusion process.

15. A heart valve prothesis according to any one of the claims 12 to 14 wherein the rod portions have rounded contours over which the leaflets roll when deflected, the leaflets being sealed to said rod portions by adhesive on surfaces thereof external to said rounded contours.

16. A heart valve prothesis according to any one of claims 12 to 15 and including a second frame comprising a rod substantially congruent with said interconnecting lobes the leaflets being sealed to and between said frames.

17. A heart valve prothesis according to any one of claims 12 to 16 wherein the free edges of the leaflets are selvages of uncut yarns.

18. A heart valve prothesis substantially as herein before described with reference to figures 1 to 8 of the drawings.

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1598111 COMPLETE SPECIFICATION
2 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheet 1

FIG. 1

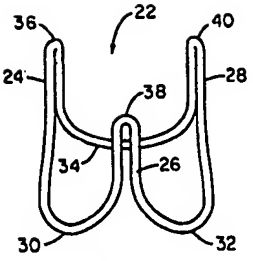


FIG. 2

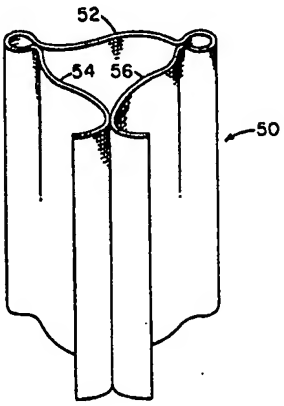


FIG. 3

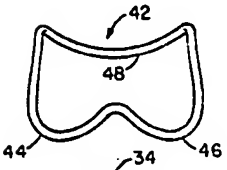


FIG. 4

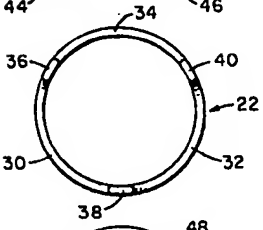


FIG. 5

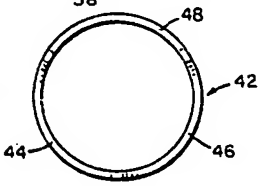


FIG. 6

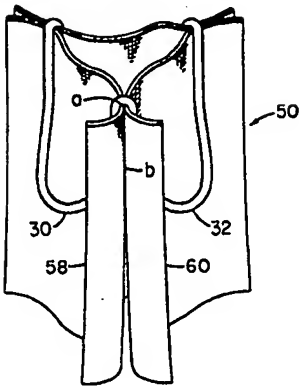


FIG. 8

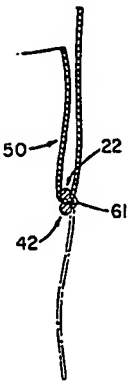


FIG. 7

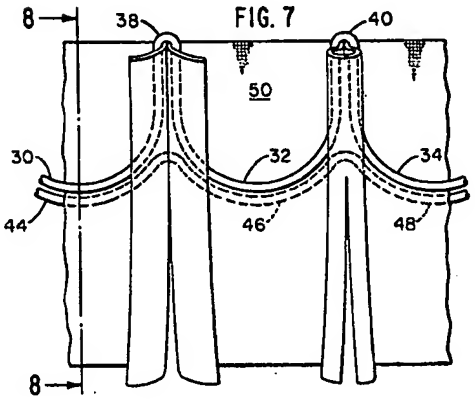
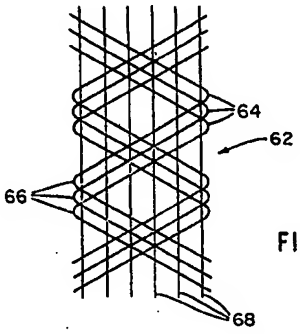


FIG. 9



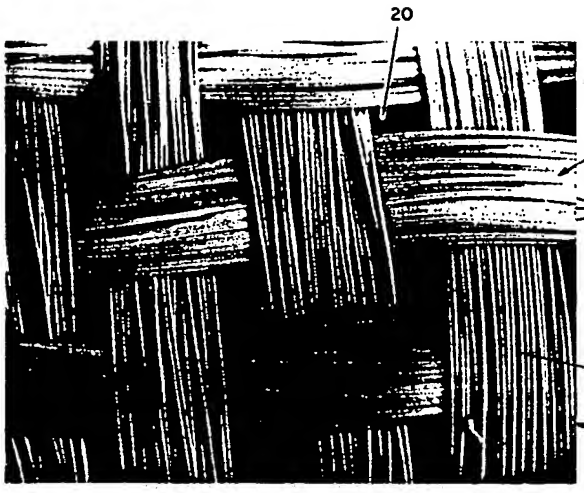


FIG.10

FIG.11